FINAL WG 3, 5/18/04

National Aquatic Animal Health Task Force-Meeting Report of Work Group 3 "Laboratory Methodologies"

USDA/APHIS Headquarters, Riverdale, Maryland. April 13-14, 2004.

Introduction:

The National Aquatic Animal Health Task Force (Task Force) has been charged by the Joint Subcommittee on Aquaculture (JSA) to develop a national aquatic animal health plan (NAAHP). The purpose of NAAHP is to: provide safe, efficient, and predictable commerce for aquatic animals: protect farmed and wild aquatic animals from the import of foreign animal diseases and pests; meet the United States' national and international aquatic animal health legal obligations; and, ensure the availability of diagnostic and certification services for private, public, and tribal aquaculture. The Task Force decided to develop the various elements of the plan in a transparent and collaborative process with its many stakeholders. The Task Force will convene work groups, which represent a broad spectrum of experts, to provide input on the various topics/elements of NAAHP. The work groups are informal in structure and are not advisory groups nor are they operating under the rules of the Federal Advisory Committee Act (FACA). Discussions of the work groups will be captured in meeting reports such as this one. These reports will in turn be used to develop draft chapters of the plan. After approval by the Task Force, the draft chapters will be submitted to JSA and our stakeholders for comment. Eventually, the finalized chapters will be adopted by the Task Force as part of NAAHP.

Participants:

Task Force: Jill Rolland (USDA/APHIS), Kevin Amos (NOAA Fisheries), and Marilyn Blair (USFWS).

Stakeholders: Robert Bakal, USFWS; Jerri Bartholomew, Oregon State University, AFS-FHS; Deborah Bouchard, Micro Technologies Inc.; Steve Ellis, USDA/APHIS; Andrew Goodwin, University of Arkansas at Pine Bluff; Donald Hoenig, American Veterinary Medical Association; Caroline O'Farell, American Type Culture Collection; Melba Reantaso, Maryland Dept. of Natural Resources; Patricia Varner, Texas Veterinary Medical Diagnostic Laboratory; Janet Warg, National Veterinary Services Laboratories.

Discussion:

The first order of business was a welcome on behalf of the entire Task Force and introductions/backgrounds of the participants. Next, an explanation was given to WG 3 on the process of NAAHP development, process for identification of work group participants, and explanation of expectations of the work group. A proposed agenda was distributed and considered by the group. The group accepted the agenda as a guideline for deliberations.

Discussions first focused on laboratory approval systems with descriptions of the APHIS, American Association of Veterinary Laboratory Diagnosticians (AAVLD), and ISO/IEC 17025 systems. Definitions of diagnostics, inspections, and surveillance were also explored as an aid to determine what these laboratories would be required to perform.

In addition, individual versus laboratory accreditation or approval was compared. Individual certifications described included American Fisheries Society-Fish Health Section (AFS-FHS), Canadian, and Title 50. Participants understood the need for a Federal system of approval/accreditation for laboratories conducting official surveillance and recognized there was merit to the system now in place operated by APHIS. It was also recognized by participants that APHIS personnel, such as those in local AVIC offices, are relatively inexperienced in aquatic animal techniques and would benefit in additional training should they be the ones who continue to approve aquatic labs. The potential exists for teams of Federal employees from APHIS, FWS, and/or NOAA to work together to inspect/approve labs. In this way, personnel from the different agencies would benefit from the expertise of others.

Next, discussions turned toward quality assurance/quality control (QA/QC) programs for laboratories. Participants described programs in place or ones they were working on incorporating at their own locations. Many felt that ring testing, inter-calibration testing, and proficiency testing would be necessary in a national QA/QC program. The FDA milk testing program was noted as an exceptional and rigorous model where individuals and the laboratories are inspected every 2 years. ISO was seen as an international system that would be beneficial to follow in the long term (recognized by trading partners), or at least to be compatible with (could avoid cost of ISO audit). However, concerns were raised that smaller laboratories would not be able to afford ISO programs nor would small producers using these labs. Questions over whether ISO programming would be needed for transfer within and between States, or if only for international shipments were raised. It was pointed out that States may have their own rules and templates, but we can provide them with a Federal model to follow.

The AFS-FHS/USFWS QA/QC manual was seen to be an excellent example of a model program to follow. FWS is considering approval of this document by ISO as it appears to be ISO compatible at this point. OIE and American Organization of Applied Communities also have QA/QC programs which were discussed but were seen to not be as specific (more than one preferred test) which would not enable comparison of results between labs as easily.

Standardization of reagents, media, cell lines, etc. was the next topic of discussion. It appeared from working group members that most sources for supplies such as cell lines included networking with other laboratories and American Type Culture Collection (ATCC). The National Veterinary Services Laboratories (NVSL) also provides, for a price, antisera and antibodies for some diseases. Standardization may be difficult for all reagents and possibly this need may be met by the QA/QC program in place including proficiency testing. It was noted that ATCC does not check for functionality but does check for contamination in cell lines. Federal agencies can not recommend or suggest the use of specific reagents. Availability of some reagents is seen to be a problem such as for reference sources for antibodies for bacterial detection. Another area of need is standard positive controls especially for polymerase chain reaction (PCR) tests. More validation and research for kits is necessary, especially as it is more difficult for multiple species.

Other suggestions included the need for a histology slide library and for more applied research such as epidemiological disease investigation.

Testing methodologies were then discussed for notifiable diseases. Again, AFS-FHS/USFWS and OIE documents were suggested for use as models. OIE was again seen as being very broad with AFS having a set test for screening for comparisons of results. However, the AFS inspection manual does have much consensus with OIE, is updated yearly, and availability of reagents is known. It was suggested that the Task Force members develop a matrix to compare OIE and AFS suggested tests to check for equivalency. It was also noted that many States are and will use the AFS Bluebook. As a case in point, one laboratory did submit the entire AFS inspection manual to APHIS for their laboratory approval. Other manuals discussed as models included the Australian manual (3 levels), and the Asian manual (Melba will send out risk assessment section).

Other benefits of the AFS manual included the use of the oversight committee which updates the manual on an annual basis to allow the manual to be very flexible and changeable. APHIS individuals could potentially be included in the oversight committee as well as the opportunity for anyone to submit comments. A shellfish/crustacean section will be added soon to the AFS manual. Need to verify if APHIS can not endorse another entity's document.

Other suggestions included sending out the notifiable pathogen list to States and industry for a survey on what they think is important. Informing States that the list is a minimum, and is not developed to hinder State programs, but that surveillance programs will be needed to add pathogens would be important.

Future needs for laboratories in aquaculture were also explored. Shellfish and crustaceans may have needs for more laboratory testing and research. However, the need for establishing a recommended national preventative health plan including surveillance testing and health inspection protocols for broodstock and/or transported seedstock of warm water species that is both cost effective and reliable appears to be of higher priority. Koi Herpes Virus and Spring Viremia of Carp Virus cases have brought out more needs for farm certifications and inspections in Arkansas. Bait and ornamental fish may see more growth in the future than other species in this area of the U.S. Marine aquaculture may be another area of growth for the future with the need for more laboratories.

Summary of issues to consider for NAAHP:

- AFS-FHS/USFWS Bluebook documents including "Suggested procedures for Aquatic Animal Health Inspections" and QA/QC sections appear to be good models for laboratory protocols and QA/QC programs.
- Need to verify if APHIS can not endorse another entity's documents, or how to incorporate into a national program.
- May be able to recognize laboratory approvals of each Federal agency or coordinate with shared necessary training and ring testing.

- If accredited veterinarians, AFS-FHS certified pathologists and inspectors are all required to comply with mandatory APHIS reporting for notifiable pathogens, there would be sufficient national reporting of notifiables.
- Development of a matrix to compare OIE and AFS-FHS manuals would be helpful to determine equivalency of both documents.
- ISO/IEC 17025 system may be the best internationally recognized program for the future.
- Needs for standardization of reagents, media, etc. may be addressed adequately in a sufficient QA/QC program.

Next Steps:

Input from WG 3 will be used in drafting portions of Chapter 5 of the NAAHP relating to laboratory methodology and approval. The draft portion of Chapter 5 will be completed by the end of 2004. At this time there does not appear to be a need to re-convene WG 3.

Feedback from Participants (7 of 9 evaluation forms collected):

- High marks were given on organization, facilitation, and meeting objectives of the workshop.
- Suggested that each agency devote a full time person to this Task Force.
- Emphasize to States and stakeholders what the goals are and what this means to them now and in the future.
- Allow opportunity for members of a WG to comment on results of another WG if expertise overlaps.
- Be sure the WG can review draft of WG report before it goes to the FEC/JSA. Possibly have conference call to discuss comments of report.
- Specific outlines indicating how decisions had been made or how programs would actually work
- Break group down into smaller groups per item after general meeting, then regroup and discuss further.
- Clearly defined questions to be addressed. Action items for the meeting.